 DEC 19 2013

Section 8 – 510(k) Summary

Date:	8 November 2013
Sponsor:	Nexxt Spine 14425 Bergen Blvd, Suite B Noblesville, IN 46060 Office: 317.436.7801 Fax: 317.245.2518
Contact Person:	Eric Lintula, Director of Engineering and Regulatory Affairs
Trade Names:	Struxxure®
Device Classification	Class II
Classification Name:	Appliance, fixation, spinal intervertebral body
Regulation:	888.3060
Device Product Code:	KWQ
Submission Purpose:	This submission adds the Struxxure® components to the Blade® System of cervical solutions.
Device Description:	Struxxure consists of plates and screws in a variety of sizes. Plates from 1- to 5-levels are offered. Fixed and variable angle screws are available in two diameters in both self-tapping and self-drilling versions.
Intended Use:	The Struxxure® System is intended for anterior screw fixation of the cervical spine. These implants have been designed to provide stabilization as an adjunct to cervical fusion. Indications for the use of this implant system include degenerative disc disease (defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fractures or dislocations), spinal stenosis, deformity (i.e., kyphosis, lordosis or scoliosis), tumor, pseudarthrosis or failed previous fusion.
Materials:	Struxxure plates and screws are manufactured from titanium (Grade 4) or titanium alloy (Ti-6Al-4V ELI) as described by ASTM F67 and ASTM F136, respectively.
Predicate Devices:	Blade® Anterior Cervical Plate System (K091936) C-Tek® MaxAn™ Anterior Cervical Plate System (K080646) ABC2 Cervical Plating System (K050813)
Performance Data:	Static and dynamic compression bending and static torsion per ASTM F1717 was used to characterize the mechanical properties of the Struxxure® components. The mechanical test results demonstrate Struxxure® to be substantially equivalent to the predicate devices.

Technological Characteristics:

The Struxxure® components possess the same technological characteristics as the predicates. These include:

- basic design (plate and screw fixation system),
- material (titanium and titanium alloy),
- sizing: sizes (diameter and lengths) are within the range of those offered in the predicate systems, and
- anatomic location.

Therefore the fundamental scientific technology of the Struxxure® System is the same as previously cleared devices.

Conclusion:

In comparison to the predicate devices, the Struxxure® Cervical Plates and Screws have

- the same intended use (as described above),
- the same technological characteristics (as described above)

Therefore the Struxxure® System can be found substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 19, 2013

Nexxt Spine LLC
Mr. Eric Lintula
Director of Engineering and Regulatory Affairs
14425 Bergen Boulevard, Suite B
Noblesville, Indiana 46060

Re: K133475
Trade/Device Name: Struxxure®
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: November 22, 2013
Received: November 25, 2013

Dear Mr. Lintula:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 7 – Indications for Use Statement

510(k) Number: K133475

Device Name: Struxxure®

Indications for Use:

The Struxxure® System is intended for anterior screw fixation of the cervical spine. These implants have been designed to provide stabilization as an adjunct to cervical fusion. Indications for the use of this implant system include degenerative disc disease (defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fractures or dislocations), spinal stenosis, deformity (i.e., kyphosis, lordosis or scoliosis), tumor, pseudarthrosis or failed previous fusion.

Prescription Use __X__ OR Over-the-Counter Use_____

(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD

Division of Orthopedic Devices